DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
FAX: 615-781-5391

June 16, 2006

WARNING LETTER NO. 2006-NOL-09

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Harry V. Floyd, President
Harry Floyd Livestock, Inc.
1798 Savannah Highway
Waynesboro, Tennessee 38485-4301

Dear Mr. Floyd:

An investigation, including an inspection of your operation, located at 1798 Savannah Highway, Waynesboro, Tennessee, on November 9, 10, 14, 22, and December 9, 2005, and an interview on May 15, 2006, conducted by a representative of the U.S. Food and Drug Administration (FDA), confirmed you offered an animal for sale for slaughter as food, which was adulterated under Sections 402(a)(2)(C)(ii) [21 *United States Code* (USC) 342 (a)(2)(C)(ii)] and 402(a)(4) [21 USC 342 (a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act). A food is adulterated under Section 402(a)(2)(C)(ii) [21 USC 342 (a)(2)(C)(ii)] of the Act if it contains a new animal drug which is unsafe within the meaning of Section 512 of the Act. You may find the Act and associated regulations through links at FDA's Internet home page at http://www.fda.gov.

On or about September 14, 2005, you sold an animal with backtag number 64 FE6769 to Harry Shelton. On or about September 22, 2005, this animal was slaughtered for food at [redacted]. The U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analyses of tissues collected from that animal identified the presence of the drug gentamicin at 5.16 parts per million (ppm) in the animal's kidney. No tolerance has been established for residues of gentamicin in the edible tissues of cattle, as codified in Title 21, *Code of Federal Regulations*, Part 556.300 (21 CFR 556.300). The presence of this drug in the edible tissues of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) [21 U.S.C. 342 (a)(2)(C)(ii)] of the Act.

Our investigation also found you hold animals under such inadequate conditions that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system to ensure medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. In addition, you failed to maintain records regarding the identity and the medicated status of the animals you purchased, transported, and delivered for sale at auction yards. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act [21 USC 342(a)(4)].

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure your overall operations and the food you distribute are in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

This is not your first tissue residue violation. Our investigation identified a previous animal, a beef cow purchased and sold by you on or about March 7, 2005, for slaughter for human food to FPL Packing Company, Inc., which contained a residue. USDA/FSIS analyses of tissues collected from that animal disclosed the presence of the drug neomycin at 5.93 ppm in the beef cow liver. A tolerance of 3.6 ppm has been established for residues of neomycin in the uncooked edible tissues of beef liver, which is listed in 21 CFR 556.430(a)(1).

Please respond in writing within fifteen (15) working days from your receipt of this letter outlining the specific steps you are taking to correct the violations, including an explanation of each step taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating corrections have been made.

Your written response should be sent to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, 2424 Edenborn Suite 410, Metairie, Louisiana 70001. If you have any questions about this letter, please contact Compliance Officer Hardin at 504-219-8818, extension 102.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483

cc: U.S. Department of Agriculture
Ellington Agricultural Center
P.O. Box 40627
Nashville, TN 37204

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Tennessee Department of Agriculture
Tennessee Board of Veterinary Medical Examiners
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